POST TITLE POSITION : Clinical Research Coordinator as CA Employee

QUALIFICATIONS REQUIRED

Applicants must address each required qualification listed below with specific information supporting each item. Failure to do so may result in a determination that the applicant is not qualified.

1. EDUCATION: A Bachelor's degree in nursing, public health , health science or science is required.

2. EXPERIENCE: At least five years' experience involved in the conduct of clinical research is required. Be knowledgeable in Good Clinical Practices (GCP); be able to assist PIs in the planning and execution of research protocol; be able to organize and maintain the Regulatory Documents; have fundamental knowledge of computer systems and information management; be able to compose Standard Operating Procedures (SOPs), Study Specific Procedures (SSPs); able to work on weekends.

3. LANGUAGE: Level IV (Fluent) speaking/reading/writing Thai, and Level III (Good working knowledge) speaking/reading/writing in English. (A copy of valid TOEIC score of at least 600 is required with your application before the deadline.

BASIC FUNCTION OF POSITION:

a. Primary agent to assist study principal investigators (PIs) in the planning and execution of clinical research approved by the appropriate institutional review boards (IRB).

b. Ensure that the conduct of the clinical research is in accordance with the approved protocol, GCP guidelines and other regulatory requirements.

c. Coordinates the creation of multiple study documents, SOPs and SSPs detailing all aspects of the conduct of the study.

d. Manages the Regulatory Documents for the study and coordinates the submission of all scientific and regulatory documents (e.g. protocols, consent forms, continuing review reports, final reports, serious adverse event) to the appropriate Regulatory Agencies. Files and formulates responses to correspondence from said agencies and committees.

e. Oversee the clinical research procedures including but not limit to screening, enrollment, and clinical follow up of research volunteers.

f. Prepares study personnel and regulatory files for inspections and audits by external Regulatory Agencies (e.g. U.S. FDA).

g. Assist the PIs in preparing study reports for IRBs and study data for presentations at international scientific meetings and manuscript submissions for publication.